DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

1692d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

August 22, 2001

Warren Goodman, M.D.
Medical Director
Prescott Imaging Center
1000 Ainsworth Drive; Suite #115
Prescott, AZ 86305-1664

W/L Number: 75 - 01
Inspection ID: 1313590021
CFN: 2029646
FEI: 1000518931

Dear Dr. Goodman:

We are writing to you because on August 8, 2001 your facility was inspected by a representative of the State of Arizona acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- Level 1: Phantom quality control (QC) records were missing for the following weeks:

September 3rd through 9th, September 24th through 30th
November 5th through 11th, November 26th through December 2nd
December 3rd through 9th, December 10th through 16th, and
December 24th through 30th of the year 2000; plus
January 14th through 20th, January 28th through February 3rd
March 4th through 10th, March 18th through 24th,
April 1st through 7th, April 8th through 14th, April 22nd through 28th
May 20th through 26th, July 8th through 14th, and
July 22nd through 28th of the year 2001

for unit #2 (a [redacted] machine, model [redacted], serial number [redacted]) which is located in mammography room #2.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

- Level 2: Corrective action before further exams (for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits) was not documented for unit #2 (a [redacted] machine, model [redacted], serial number [redacted] which is located in mammography room #2.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-8404
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number 1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number 949-798-7708.

Sincerely,

Daniel E. Rowland for
ADD

Alonza E. Cruse
District Director

cc:

Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191-4397

Arizona Radiation Regulatory Agency
Attention: Ms Shanna Farish
4814 South 40th Street
Phoenix, AZ 85040-2968